

## **REMARKS**

Applicant notes with appreciation the interview courteously afforded the undersigned counsel for the Applicant on February 11, 2004. At the interview, the content of the Final Rejection dated December 23, 2003 was discussed. In that Final Rejection claims 1-4 and 7-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ward et al. Further details of that rejection will be discussed below, however, it was noted at the interview that the Examiner stated at the bottom of page 2 of the Office Action that the Ward et al reference does not explicitly disclose an excitable cell detector adapted to detect excitable cell signals related to the respiration of the user, however, the Examiner did not clearly identify structure or components in the Ward et al reference that would justify the rejection under Section 103(a) despite the lack of an explicit disclosure of an excitable cell detector.

The Examiner used reference numeral 18 in this context, which refers to a breathing detector 18 in the Ward et al reference, however, in view of the phrase "but does not explicitly disclose" in the penultimate line at page 2 of the rejection, the purpose of designating reference numeral 18 at that location is unclear.

Moreover, as also discussed at the interview, claims 5, 6 and 13-15 were stated to be rejected under 35 U.S.C. §103(a) as unpatentable over Sinderby at the top of page 4 of the Final Rejection, however, in the more detailed substantiation of this rejection, it appears that the Examiner is also relying on the Ward et al reference as a basis for this rejection. This same rejection was made in the July 22, 2003 Office Action, and the lack of clarity of that rejection was pointed out in the second full paragraph at page 7 of Applicant's response to that earlier rejection. Nevertheless, in the third paragraph on page 5 of the Final Rejection, The Examiner

addressed only the Ward et al "stand alone" rejection, but did not clarify the rejection based on the Sinderby reference.

For all of these reasons, it was agreed at the interview that the finality of the rejection would be withdrawn, and prosecution would be reopened.

In the Final Rejection, in response to the arguments made by the Applicant in the amendment filed October 14, 2003, the Examiner stated that independent apparatus claim 8 sets forth functions for various components, but the Examiner apparently believed the claim language did not require the Examiner to give those functions significant patentable weight. The Examiner stated there is no need to have motivation, disclosure or teaching for something that is not positively claimed. The Examiner stated that by disclosing a processor, the Ward et al reference meets all of the limitations that Applicant has positively set forth.

In response, Applicant respectfully submits that independent apparatus claim 8, in the form previously presented, although describing various components in terms of their function, did so in a manner that did not permit the Examiner to ignore those functions in assessing the patentability of the combination of claim 8. Nevertheless, claim 8 has been amended to explicitly describe each of the named claim elements as being "for" performing a designated function. This is not an attempt to "convert" claim 8 into a "means-plus-function" claim, however, under the guidelines set forth in MPEP Section 2114, it is clear that claim limitations that are not precisely in "means-plus-function" form can be given patentable weight, despite the use of functional language. Applicant respectfully submits that independent claim 8 satisfies all of the requirements set forth in MPEP Section 2114 for giving patentable weight to the functional language set forth in claim 8.

Moreover, Applicant does not agree that the Ward et al reference provides clear teachings that the control unit 30 thereof is a programmable computer or processor. The Examiner has apparently made this assumption on the basis of the language at column 5, line 57 of the Ward et al reference, which states that the control unit is supplied with "programmed data from the user interface 6A." Nowhere in the Ward et al reference, however is the control unit 30 ever referred to as itself being programmable, or being a processor or a computer, much less a general purpose computer. Even if the control unit 30 could be considered some type of processor, there is no teaching whatsoever in the Ward et al reference that it could be reprogrammed to operate in a manner different from the manner specifically described in the Ward et al reference.

In the context of the control unit 30, the entry of "programmed data" clearly means the settings which are selected by a physician. A person of ordinary skill in the art would not expect that every time the apparatus disclosed in the Ward et al reference is to be used, it must be "programmed" in the sense of programming an operating program.

The manner of operation of the apparatus disclosed in the Ward et al reference is different from the claimed manner of operation. In view of the patentable weight which must be given to the functional language in apparatus claim 8, and in view of the lack of teaching of a programmable processor or computer in the Ward et al reference, Applicant does not agree with the Examiner's conclusion that the Ward et al reference sets forth sufficient structure to meet the positively claimed elements of claim 8 of the present application.

In the Ward et al reference, the breathing detector 18 can receive intrinsic nerve impulses from the patient, such as from the phrenic nerve. These signals that are indicative of breathing, however, are not used to change any of the basic ventilator settings that constitute the "programmed data" entered by a physician. The detection of the breathing signals is used in the Ward et al reference to *augment*, as necessary, ventilation that takes place using the ventilator 6 with muscle stimulation provided by the muscle stimulation apparatus 14. As described in the paragraph at column 5, lines 58-63, as long as adequate breathing signals are detected, these signals are used to synchronize operation of the ventilator 6. *Additional assistance* (emphasis added) is stated to be provided via the muscle stimulation apparatus 14. This is explained in more detail in column 6, lines 1-13, wherein it is clear that the muscle stimulation, if it occurs, is undertaken *in addition to* the ventilation therapy provided by the ventilator 6, such as providing a muscle stimulation at every tenth breathing cycle.

Therefore, even though a signal is obtained in the Ward et al reference that might be considered as a signal from an excitable cell, this signal is only used in the Ward et al reference to *augment* ventilation therapy with another, different therapy (muscle stimulation), but is not used to *change* any part of the existing ventilation therapy, that has already been set by a physician.

This is in contrast to the subject matter of claim 8 which requires a control unit that controls the pneumatic unit, which does so based on a trigger requirement for respiration, with the trigger requirement being adapted by an adaptation unit dependent on the second respiration indicator signal that, in turn, is dependent on the excitable cell signals. Therefore, in the subject matter disclosed and claimed in

the present application, a parameter relating to the actual ventilator treatment itself, namely the trigger requirement, is adapted dependent on the excitable cell signals.

The apparatus disclosed in the Ward et al reference does not operate in that manner, and there is no teaching in that reference to teach, motivate or induce a person of ordinary skill in the art to modify the operation of the Ward et al reference so as to cause the components thereof to perform the functions set forth in claim 8. As noted above, the control unit 30 in the Ward et al reference is nowhere described as a computer that can be reprogrammed so as to depart from the manner of operation explained in the Ward et al reference, however, even if this were so, basing a rejection under Section 103(a) on the ability of a person of ordinary skill in the art to reprogram the control unit 30 in the Ward et al reference would be no more than an "obvious to try" rejection, which is not justifiable as a basis under Section 103(a).

As to method claim 1 and the claims depending therefrom The Examiner stated the method "would naturally flow" from the apparatus but, as noted above, the Examiner believed it was not necessary to take the functional language in the apparatus claims into account in assessing their patentability. Applicant submits that the Examiner had no basis whatsoever for ignoring the functional limitations in such a method claim, since a method claim necessarily must be set forth in functional language. For the same reasons discussed above in connection with claim 8, these limitations in claim 1 are not disclosed in the Ward et al reference.

As to claims 5, 6 and 13-15, the Examiner relied on the Sinderby reference as disclosing a muscle signal sensor. Applicant does not disagree that the Sinderby reference discloses such a sensor, however, the most that can be said if the Ward et

al apparatus were modified in accordance with the teachings of Sinderby is that such a muscle signal sensor would be used in place of the aforementioned phrenic nerve sensor. Even if muscle signals were employed instead of the aforementioned breathing signals in Ward et al, this would not alter the basic operation thereof, as described above, which is significantly different from the subject matter of claims 1 and 8, from which claims 5 and 6 and 13-15 respectively depend.

All claims of the application are therefore submitted to be in condition for allowance. In view of the agreement reached at the interview that the finality of the rejection would be withdrawn, reconsideration of the application on the basis of the claims presented herein is respectfully requested.

Submitted by,



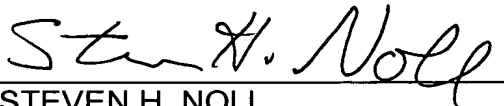
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